

REMARKS

Claims 35, 37, 38, 40-42, 47, and 59 are currently pending in the application. Claims 37, 41 and 42 have been found to be allowable. Claims 60-65 are added. The newly added claims find support throughout the specification (particularly at pages 6-8) and in the claims as originally filed. No new matter is added.

Formal Matters

Specification

The Examiner indicates that sequences appear in the specification which are not identified by SEQ ID NO as required by 37 C.F.R. §1.821(d). Applicants submit that they have amended the specification to include appropriate reference to the SEQ ID Nos set forth in the previously filed sequence listing.

Rejection of claims 40, 47, and 59 Under 35 U.S.C. §103(a)

The Examiner has rejected claims 40, 47, and 59 under 35 U.S.C. §103(a) as being obvious over Grandy et al. (U.S. Pat. No. 5,837,809). The Examiner asserts that Grandy teaches ligands for mammalian opioid receptors having a sequence which is 100% identical to the sequence of SEQ ID NO: 2 of the present invention. The Examiner asserts that Grandy teaches that the peptide can be produced by molecular or genetic engineering means, and that transformed host cells comprising vectors encoding the protein are also taught. The Examiner concludes that it would have been obvious to one of skill in the art to make a nucleic acid encoding the peptide of SEQ ID NO: 2. Applicants respectfully traverse the rejection.

Applicants submit that Grandy et al. is not prior art to Applicant's claimed invention. Applicants have established, by the Declaration of Mr. Daniel Altman under 37 C.F.R. §1.132 filed herewith, that the present invention was conceived and reduced to practice prior to the earliest effective filing date of Grandy et al. Applicants therefore request that the rejection be reconsidered and withdrawn.

In addition, Applicants have resubmitted previously cancelled claim 39 (now claim 60), as well as new claims 61-65, drawn to screening methods (analogous to previously pending claims 51 and 52), which had been previously cancelled in view of the Grandy et al. reference. Applicants submit that, like currently pending claims 35, 37, 38, 40-42, 47, and 59, new claims 60-65 are not anticipated or made obvious by Grandy et al., in view of the §1.132 Declaration filed herewith.

Applicants submit that Grandy et al. is not prior art to Applicants' invention. Applicants submit herewith a Declaration under 37 C.F.R. §1.132, by Daniel Altman, Partner at Knobbe, Martens, Olson, & Bear ("Knobbe"), establishing that his firm received a facsimile copy of the present specification for filing as a Provisional Application (USSN 60/002,368, filed August 15, 1995, to which the present application claims priority) in the U.S. prior to the earliest filing date of Grandy et al. Thus, the §1.132 Declaration of Mr. Altman establishes that the invention claimed in currently pending claims 35, 37, 38, 40-42, 47, 59, and 60-65 was conceived and reduced to practice in the U.S. prior to the earliest filing date of Grandy et al.

Prior to the earliest filing date of Grandy et al. (August 11, 1995), Applicants' claimed invention was conceived and reduced to practice as evidenced by the following facts.

1. On August 2, 1995, a letter (Exhibit A) was sent from Office Van Maldren (Belgium; acting at that time as European counsel to Applicants) to Mr. Altman indicating that a document would be sent to Mr. Altman entitled "Ligand of the ORL₁ Receptor" for filing as a Provisional Application in the U.S. The letter of August 2, 1995 also requested that Mr. Altman prepare an assignment to be signed by the inventors.

2. On August 3, 1995, a letter (Exhibit B) was sent from Knobbe to Office Van Maldren indicating that action was being taken on the request set forth in the August 2nd letter.

3. On August 4, 1995, a letter (Exhibit C) was sent from Knobbe to Office Van Maldren enclosing an assignment and small entity declaration for signature by Applicants.

4. On August 7, 1995, a letter (Exhibit D) was sent via facsimile from Office Van Maldren to Mr. Altman enclosing two specifications (one of which was the specification for the

60/002,368 provisional application), and requesting that the specifications be filed in the U.S. as Provisional patent applications.

5. On August 8, 1995, a facsimile transmittal sheet (Exhibit E) was sent from Knobbe to Office Van Maldren indicating that Knobbe was in receipt of the facsimile letter of August 7, 1995, and that they would await the original copies of the documents to arrive by regular mail before filing in the U.S.

6. On August 14, 1995, the original copy of the letter (Exhibit F(1) and (2)) of August 7, 1995 from Office Van Maldren to Mr. Altman was received by Knobbe. Exhibit F1 shows the front of the original copy of the August 7, 1995 letter indicating that the letter had been previously transmitted by telecopier. Exhibit F2 shows the reverse side of the original copy of the letter of August 7, 1995, and shows that the original copy of the letter was received and date stamped by Knobbe on August 14, 1995.

7. On August 15, 1995, U.S. Provisional Application Serial No. 60/002,368 was filed in the U.S. Patent Office.

Thus, Applicants' claimed invention was conceived and reduced to practice in the U.S. prior to the earliest effective filing date of Grandy et al. Applicants submit that it is well settled law that the submission of a draft application to a U.S. patent attorney/agent for filing in the U.S. PTO is sufficient to establish a date of conception in the U.S. (See, e.g., *In re Mulder and Wulms*, 716 F.2d 1542 (Fed. Cir. 1983); *Ex Parte Hachiken and Ogino*, 223 USPQ 879 (1984); Exhibits G and H). 37 C.F.R. §1.132 establishes that to antedate a prior art reference, conception of the invention prior to the effective date of the reference must be coupled with due diligence from said date to a subsequent reduction to practice or to the filing of the application. MPEP 2141 (citing *Bey v. Kollonitsch*, 866 F.2d 1024 (Fed. Cir. 1986)) establishes that "reasonable diligence is all that is required of the attorney" (See, *Ex Parte Hachiken and Ogino*, 223 USPQ at 879 (where a gap of seventeen days between receipt of an initial translation of a patent application by U.S. counsel and the eventual filing of the application in the U.S. was deemed by the examiner have met the requisite diligence standard)).

In the present case, a draft of the priority specification was received in the U.S. on August 7, 1995, and thus established the conception of the presently claimed invention in the U.S. As indicated above, Mr. Altman was waiting to receive by regular mail, the original documents for filing in the U.S. It took seven days for the documents to reach Mr. Altman in California from Brussels, Belgium. Upon receipt, Mr. Altman filed the provisional application the following day. Applicants submit that the record shows that with the exception of the seven days it took for the documents to reach Mr. Altman by mail, action was taken in the preparation of the priority provisional application on consecutive day from August 7-8 and 14-15. Thus, Applicants submit that Mr. Altman's Rule 132 Declaration establishes that the present invention was conceived in the U.S. prior to the earliest effective filing date of Grandy et al., and was diligently reduced to practice via the filing of U.S. Provisional Application No. 60/002,368 on August 15, 1995.

In view of the Rule 132 Declaration by Mr. Altman, setting forth a date of invention of the present claims prior to the August 11, 1995 filing date of Grandy et al., Applicants submit that Grandy et al. is not prior art over the claimed invention. Applicants accordingly request withdrawal of the rejection under §103 (and any accompanying rejection under §102 or §103 over Grandy et al. which may apply to newly added claims 60-65) over Grandy et al.

Applicants submit that in view of the foregoing remarks, all issues relevant to patentability raised in the Office Action have been addressed. Applicants respectfully request the withdrawal of rejections over the claims of the present invention.

Respectfully submitted,

Date: July 15, 2003



Name: Kathleen M. Williams
Registration No.: 34,380
Customer No.: 29933
Palmer & Dodge LLP
111 Huntington Avenue
Boston, MA 02199-7613
Tel. (617) 239-0100